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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/862,690	05/22/2001	Robert John Cottone, JR.	1133279-0004	8698

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PATENT DEPARTMENT
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NEW YORK, NY 10036

EXAMINER

WEBB, SARAH K

ART UNIT PAPER NUMBER

3731

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/862,690

Applicant(s)

COTTONE, ET AL.

Examiner

Sarah K Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-10 and 12-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-10 and 12-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claim 12 is objected to because of the following informalities: "the closed circumferential element" is not mentioned in claim 8, from which claim 12 depends. Examiner suggests changing the dependency of this claim so that it depends from claim 10. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

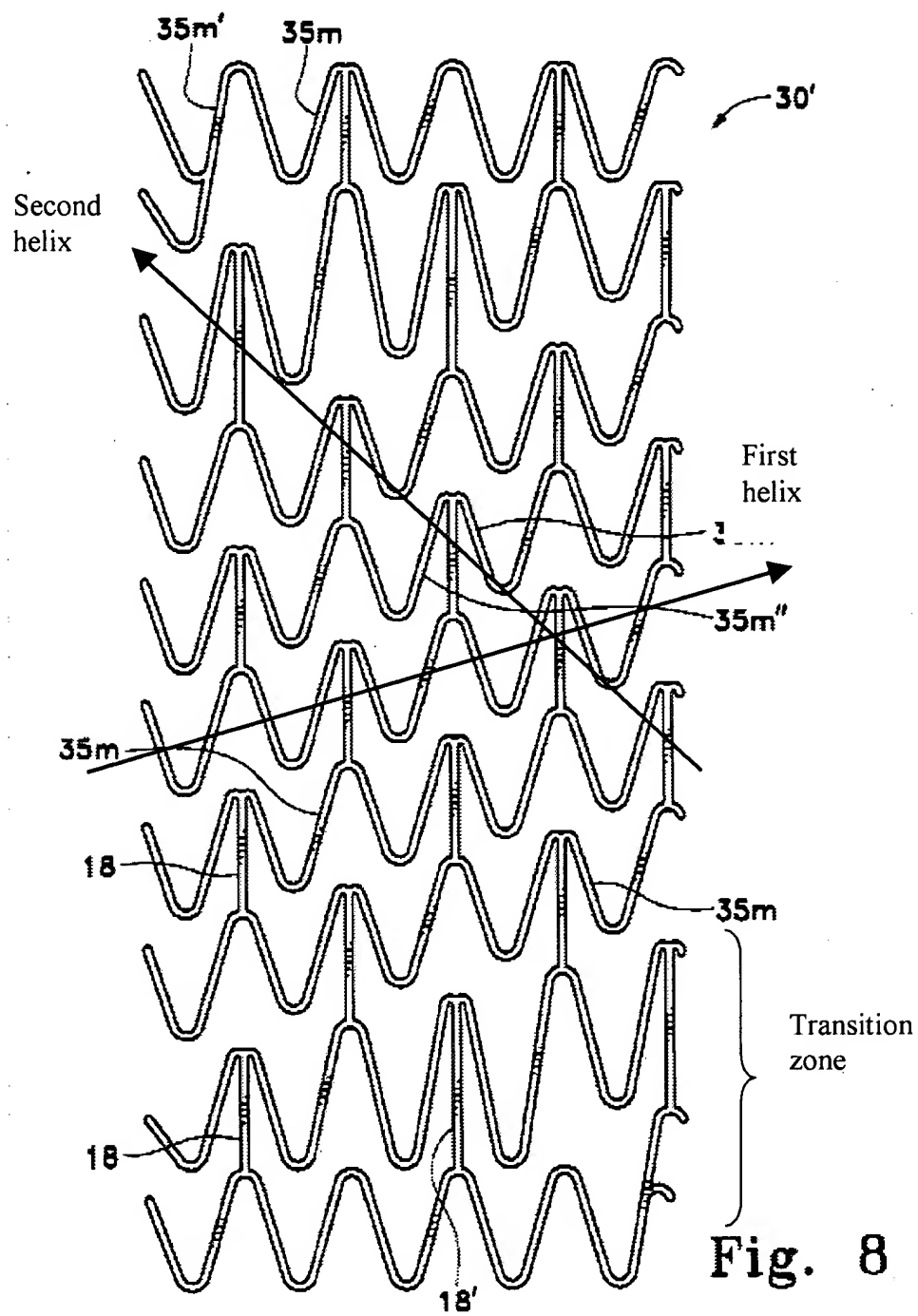
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-6,8,9,14-21,24-29,32, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,925,061 to Ogi et al.

As most clearly shown in Figure 8 below, the stent pattern includes a first helix comprising a plurality of nonsinusoidal zigzags, a second helix comprising a plurality of elongate links (18) that connect fewer than all the undulations, and both helices proceed along the entire length of the stent. The links extend between junction points, or peaks, of adjacent turns of the helix. Ogi explains that there should be two to four links per turn of the helix (column 5, lines 7-10). Further, the stent has no free ends, since there are transition zones at both ends of the stent. The transition zones include undulations of increasing amplitude and a closed loop of the first helix. The material for the stent can be nickel-titanium alloy (column 6, line 16).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 10,12,22, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogi et al. in view of US Patent No. 6,352,552 to Levinson et al.

Ogi fails to include closed circumferential elements located at each end of the stent. Levinson discloses a very similar stent pattern to Ogi. The pattern includes a continuous sinusoidal helix and links between adjacent turns. Levinson teaches that closed circumferential elements should be located at both ends of the helix and connected to the helix by links. This provides a highly flexible stent that also has good strength and support capability. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include closed circumferential elements at each end of the Levinson stent, as Levinson teaches that this configuration produces a highly flexible, yet strong and supportive stent.

3. Claims 13,23, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogi in view of Levinson, as applied above, and further in view of US Patent No. 6,315,794 to Richter.

Ogi and Levinson fail to form the closed end elements from radiopaque material. Richter discloses a stent in Figure 3A that has zigzag rings connected by links. Richter teaches that the closed circumferential elements (111,112) on either end of a

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stent should be radiopaque, because this type of marking is useful for accurate positioning of the ends of the stent in critical circumstances (column 4, lines 50-65). Richter goes on to state that the elements (11,112) are formed of suitable radiopaque materials, such as gold and silver. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the closed circumferential elements of the modified Ogi stent from a radiopaque material, as taught by Richter, in order to provide greater accuracy in positioning of the stent.

Response to Arguments

4. Applicant's arguments, see pages 10-16, filed 5/23/05, with respect to the rejection(s) under Cottone have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Ogi et al.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patents 6,042,597 (Kveen et al.) and 6,551,351 (Smith et al) disclose stent patterns with a first undulating helix and a second helix formed by links.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
6/15/05

SKW

Julian W. Woo

**JULIAN W. WOO
PRIMARY EXAMINER**